Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model): *Estimation of Lead Exposure from Water Sources for U.S. Children: Water Consumption*

Peer Review Report

Prepared by:

TRW Lead Committee

Date:

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EXECUTIVE SUMMARY

The Peer Review Panel (herein referred to as Panel) reviewed a document titled *Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model), Estimation of Lead Exposure from Water Sources for U.S. Children: Water Consumption* (herein referred to as the Update Document) to address 14 charge questions regarding the information contained in the document.

The Update Document presented a summary of the published literature and an analysis of the available data regarding nationally representative water consumption rates for children in the United States.

This Peer Review Report is intended to provide a summary of the Panel's comments and the TRW Lead Committee's revisions to the Update Document in response to the Panel's recommendations.

The Panel's review resulted in an editorial revision of the Update Document. The Panel's findings are summarized below in Section 2.2 Summary of Findings and Section 3.0 Results. The revised final Update document may be found at http://epa.gov/superfund/lead/trw.htm.

1.0 INTRODUCTION

1.1 Background

The default background values for the *Water Consumption* variable in the IEUBK model represent age-specific central tendency estimates for lead intake from water in the absence of exposures at the site being assessed. The default consumption rates were derived from the water (and water-based foods) consumption values from the U.S. Department of Agriculture's 1977-78 Nationwide Food Consumption Survey (NFCS; USDA, 1984) and the Department of Health and Human Services 1976-80 National Health and Nutrition Examination Survey (NHANES; U.S. DHHS, 1983) as reported in the Exposure Factors Handbook (U.S. EPA, 1989). Of the approximately [redacted] foods obtained from the NFCS and NHANES surveys, a representative list of commonly consumed water-based foods (water, coffee, tea, reconstituted juices, and reconstituted soups) was paired with the daily water intake information from the NFCS and used to predict total water consumption in the United States (Pennington, 1983; U.S. EPA, 1989).

The purpose of the Update Document was to provide a recommendation for revising the *Water Consumption* variable in the IEUBK model using a more representative methodology for estimating water consumption, and more recent daily average water consumption rates. Updating the IEUBK model default values may be considered appropriate if evidence is sufficient to indicate that a newer, more representative data and methodologies for calculating water consumption rates are available that would be more protective for site risk assessment.

The Update Document presents an analysis of the available data regarding childhood water consumption. The principal objectives of the review and data analysis were to:

1. Identify published literature potentially relevant to estimating water consumption rates in children. Select studies that meet predetermined quality considerations.

2. Evaluate data contained in the pertinent national databases to examine whether they are adequate and sufficient to conclude that the current IEUBK model default values for water consumption are representative (or not) for residential scenarios at Superfund sites.

3. Consider use of these data, if adequate and sufficient, to recommend quantitative central tendency estimates for water consumption for use in the IEUBK model.

This Peer Review Report was prepared to provide a summary of the Panel's comments and the TRW Lead Committee's revisions to the Update Document in response to the Panel's recommendations.

2.0 PEER REVIEW PROCESS

2.1 Peer Review Charge

The Update Document qualifies as a technical document and is eligible for an independent peer review of the content. U.S. EPA contracted Environmental Management Support, Inc. (EMS) to conduct an independent peer review of the Update Document. EMS conducted the review of the technical document in accordance with the U.S. EPA's Science Policy Council

Peer Review Handbook (U.S. EPA, 2006). Management of the review consisted of the following general activities:

- Identified areas of expertise necessary for a scientifically rigorous review.
- Identified a list of candidate expert peer reviewers.
- Evaluated the expertise of each of the candidate expert peer reviewers.
- Created a short list of candidate expert peer reviewers.
- Determined the interest and availability of the short list of candidate expert peer reviewers.
- Determined for each of the remaining list of candidate peer reviewers any potential conflict of interest or lack of impartiality, or the appearance of any potential conflict of interest or lack of impartiality; excluding candidates with either.
- Finalized a team of three expert peer reviewers.
- Developed charge questions in conjunction with U.S. EPA for the conduct of the peer review.
- Initiated the review.
- Coordinated the peer reviewers to finalize their written reviews.

The peer review was conducted as a letter review. Each reviewer was provided a copy of the Update Document and charge questions.

In seeking candidates to serve as peer reviewers, as well as selecting the final team of reviewers, an effort was made to include individuals with expertise in one of more of the areas identified by U.S. EPA:

- Water Consumption
- Lead Toxicokinetics and Toxicokinetics Modeling
- Risk Assessment or Exposure Assessment
- Toxicology
- Mathematics
- Environmental Health, Science, or Environmental Engineering

The final team of expert reviewers on the Panel consisted of the following:

- Dr. Serap Erdal, University of Illinois – Chicago School of Public Health;
- Dr. John Meeker, University of Michigan School of Public Health; and
- Dr. Paul Mushak, PB Associates.

The TRW Lead Committee thanks the Panel for providing valuable comments on the Update Document.

Efforts were made to ensure that each Panel member was allowed sufficient time to complete their review. Upon receipt by EMS, each letter review was examined and formatted for delivery to U.S. EPA. A brief summary of the Panel's findings is included in Section 3.1. U.S. EPA's charge to the Panel and a summary of the Panel's findings is included below. A summary of the Panel's comments are included as an appendix to this document.

2.2 Summary of Findings

- The Panel agreed that the CSFII database outlined in the Update Document was appropriate; however, the Panel agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support using this database over the 2003-04 and 2005-06 NHANES WWEIA database.

- The Panel also agreed that the Update Document needs to provide additional information to support using linear interpolation to estimate water consumption by age.

3.0 RESULTS

The Panel's review comments were reviewed and considered by the TRW Lead Committee and resulted primarily in an editorial revision and overall reorganization of the data presented in the Update Document. The Panel recommended revising the Update Document's organization, but did not alter the scientific methodologies, including the database used (Section 3.1). In addition to the reorganization, text was added to the Update Document to clarify the objective and findings based on the comments received from the Panel. Sections were retitled and reorganized as the following:

Peer Review Draft	Revised Draft
Overview	Overview
Analysis	Introduction
References	Technical Analysis
	Uncertainty
	Results
	Recommendations for the IEUBK Model
	Impact on the IEUBK Model Predictions
	References

The Panel provided a combined total of 50 comments. The majority of the comments were directed towards reorganizing the document for clarity. Each comment was reviewed by the TRW Lead Committee and resolutions were incorporated into a revised draft.

Based on the review of the Update Document, the Panel's overall recommendation for the update of the *Water Consumption* variable in the IEUBK model was: **Acceptable with minor revision (as indicated).**

The Appendix presents a summary of peer review questions and comments.

3.1 Selected Comments

Representative comments were selected to demonstrate the process and overall consensus of the peer review. In the text below black indicates original text, red indicates new text, and strikeout indicates deleted text.

COMMENT (1): The inclusion of more details in certain areas may help the flow of information and more clearly state the options and justification for the decision to use the selected data. For example, further background information could be included on why this was being considered, more details on the data sources being considered, how this relates to the exposure factors handbook and that process, more details on the methods used for the linear interpolation performed in Table 1 and, finally, a conclusion paragraph.

COMMENT (2): The draft does contain much of the data needed for an analysis of default values for children's water Pb consumption rates in the IEUBK model. The analysis needs completeness and clarity. As I recommended with the other drafts, the draft can be expanded with added sections. Such added headings could include "Results" or "Analysis and Results", "Implications" for the IEUBK model, "Limitations of the Methodologies", "Scope of the Methodologies"... Use of more sections with their discussions would help. The draft could benefit with some rearrangement of the information and the data sets.

Response to Comments 1 & 2: The Update Document was reorganized for clarity and additional sections and text were added describing how the water consumption values were calculated. Specifically, an 'Introduction', 'Technical Analysis', 'Uncertainty', 'Results', 'Recommendations for the IEUBK Model' and 'Impacts on the IEUBK Model Predictions' sections were added.

COMMENT (3): Table 4, providing sample size comparisons of the Kahn and Stralka, 2009 analyses with the NHANES/WWEIA 2003-06 data set, appears out of nowhere and needs discussion in the text along with the logic for its inclusion. While the sampling sizes are greater with the CSFII versus the NHANES data sets, sample size beyond a minimum count requirement is but one criterion for judging the overall validity of data. Did the authors analyze the NHANES 2003-06 dataset beyond simply comparing sample sizes? A data set with smaller sample size, but a representative size nonetheless, may have other strengths that justify its inclusion for analyses. Inclusion of Table 4 and the associated short single paragraph piques the reader's interest as to what values arise from the NHANES data. In any case, more needs to be said about the NHANES 2003-06 dataset, including why analyses were not at least attempted with the NHANES data.

COMMENT (4): As to weaknesses in the overall approach, the authors should note why there were no analyses of the NHANES 2003-06 data set, a data set that was gathered later than the 1994-1996, 1998 CSFII sets. The later NHANES set would, as recognized by the authors, account for more changes in water consumption patterns in the U.S. The authors note that the NHANES data would better capture the increase in bottled water use.

COMMENT (5): Particularly, the analysis does not fully take advantage of the NHANES 2003-2006 data. It does list at the end of the document the differences between CSFII and NHANES data sets but it omits any data analysis using the NHANES data set.

Response to Comments 3, 4 & 5: Additional text was added to the Update Document to explain using the 1994-96 and 1998 CSFII databases instead of the 2003-04 and 2005-06 NHANES WWEIA data.

Revised text:

TECHNICAL ANALYSIS

Information on dietary intakes, including water consumption, was extracted from the NHANES WWEIA data files (U.S. CDC, 2010a,b). Data from the two most recent year cycles (2003-04 & 2005-06)[1] were used, in accordance with U.S. CDC recommendations (U.S. CDC, 2006). A comparison of the sample sizes available from the 2003-04 and 2005-06 WWEIA and the 1994-96 & 1998 CSFII survey data are provided in Table 4.

~~The TRW Lead Committee also compared the CSFII 1994-96, 1998 data set (USDA, 2000) to the more recent National Health and Nutrition Examination Survey [(NHANES 2003-06); dietary intake taken data from *What We Eat in America* (WWEIA)]. The major differences were: (1) both studies were designed to estimate dietary intake for the non-institutionalized U.S. population[2]; (2) sample sizes reported by Kahn and Stralka (2009) show the CSFII 1994-96, 1998 sample sizes are at least twice the sample size available in the NHANES WWEIA 2003-06 data (Table 4); and (3) bottled water consumption has increased since the time of the CSFII 1994-96, 1998 survey.~~

Table 4. Sample size comparison (number of participants) by age range for the CSFII as compared to NHANES (WWEIA) 2003-2004 and 2005-2006. -The number of survey participants are shown in parentheses.

CSFII 1994-96 & 1998[a]	NHANES (WWEIA) 2003-2006 (IEUBK Age groups)[b]
[redacted]	[redacted]

[a] Source: Kahn and Stralka, 2009; Table 1. Consumers only, ~~All Water Sources.~~Total Water.

[b] Sample sizes correspond to individuals with two days of complete and reliable dietary recall data (CDC, 2010a, b).

New Sections Added:

UNCERTAINTY

Based on the evaluation of the 2003-2004 and 2005-2006 NHANES WWEIA data (US CDC, 2010 a,b), the biggest difference between the types and amount of water consumed currently and the types and amount of water consumed at the time of the CSFII 1994-96 and 1998 surveys may be found in bottled water. However, if the concern is exposure to lead in drinking water derived from the site, bottled water may not be a concern (i.e., the community water consumption rates recommended in this report do not include bottled water).

[1] The 2003-04 & 2005-06 dietary data were the most recent available data at the time this research was initiated.

[2] The CSFII 1994-96, 1998 does not identify subpopulations (income level, ethnicity), while the NHANES survey does

RECOMMENDATIONS FOR THE IEUBK MODEL
The TRW elected to use the consumption rate estimates by Kahn And Stralka (2009) over the 2003-04 and 2005-06 NHANES WWEIA because the 1994-1996 and 1998 CSFII database: a) included more survey participants, b) received a high level of peer review (U.S. EPA, 2011, 2010), and c) the sources of uncertainty were minimal (U.S. EPA, 2009).

COMMENT (6): Adding a discussion of the overall end results of the updated values and potential consequences of making these updates to the water consumption estimates vs. not making these updates may further support the decision for the new values. For example, the updated consumption values would be slightly higher for a number of age groups but lower for ages [redacted] to [redacted] Are these differences expected to result in large changes to the downstream uses of these data for risk assessment and decision-making?

Response to Comment 6: With the reorganization of the Update Document, an additional section (including a summary table) was added to illustrate the impact of the recommended changes on the IEUBK model predictions.

New Section Added:
IMPACT ON THE IEUBK MODEL PREDICTIONS
Using current IEUBK model defaults for all other parameters while implementing the recommended water consumption rates will increase the GM PbB for children [redacted] years of age) from [redacted] ug Pb/dL to [redacted] ug/dL. Table 5 presents the updated estimates. As shown in Table 5, the recommended changes do not have a significant impact on the probability of the geometric mean exceeding [redacted] ug/dL nor do they impact PRGs in the soil lead concentration range (in the interest for OSRTI).

Table 5. Effects of changing the water consumption variable in the IEUBK model

Source	Age Range (months)							GM	P_{10}	PRG for 5% NTE 5 µg/dL	PRG for 5% NTE 10 µg/dL
	[redacted]										
IEUBK Model Default Value[a]											
Consumption Rate (L/day)	[redacted]							[redacted]			
Lead Uptake from Water (µg/day)	[redacted]										
Calculated Total Lead Uptake (µg/day)	[redacted]										
Calculated Blood Lead Concentration (µg/dL)	[redacted]										
Recommended IEUBK Model Default Value[b]											
Consumption Rate (L/day)	[redacted]							[redacted]			
Lead Uptake from Water (µg/day)	[redacted]										
Calculated Total Lead Uptake (µg/day)	[redacted]										
Calculated Blood Lead Concentration (µg/dL)	[redacted]										

GM: Geometric mean blood lead concentration (µg/dL) for [redacted] month age range; NTE: Not to Exceed; P10: Probability of the predicted GM blood lead concentration [redacted] µg/dL; PRG: preliminary remediation goal; NTE: not to exceed

[a] *IEUBK Model (v. 1.1, build 11)*

[b] *Kahn and Stralka, 2009; all water sources, consumers only*

4.0 REFERENCES

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U.S. Environmental Protection Agency (US EPA). 2011. Exposure Factors Handbook (Final). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-09/052F, 2011.

Appendix – Peer Review Comments

CHARGE QUESTIONS to REVIEWERS

for Peer Review of

"Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model), *Estimation of Lead Exposure from Water Sources for U.S. Children: Water Consumption*"

December 2012

U.S. Environmental Protection Agency (U.S. EPA). Updating the Default Input Values for Exposure Variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK Model), *Estimation of Lead Exposure from Water Sources for U.S. Children: Water Consumption.*

Background:
U.S. EPA is seeking external peer review of the scientific basis supporting the update of several exposure variables in the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model). The IEUBK model was developed to evaluate exposure of children ([redacted]months) to lead and is used to assess risk and support environmental cleanup decisions at current or potential Superfund sites. The IEUBK model is maintained by U.S. EPA's Technical Review Workgroup (TRW) Lead Committee.

The TRW Lead Committee has identified recent data that provide a more scientifically sound basis to develop nationally-representative, age-group specific default values for intake rates of lead in children. Given the available data, the TRW Lead Committee recommends updating the IEUBK model default values for the bioavailability of lead in soil and dust, water lead concentration in the United States, as well as water consumption, dietary consumption, and ventilation rates in children in the United States.

The current draft recommendations include updates to the bioavailability of lead in soil and dust, national drinking water lead concentration, as well as age-specific water, air, and food intake values. Because site-specific information is generally preferred to default values for exposure variables in the IEUBK model, it is anticipated that some of these defaults may be replaced with site-specific information. The goal of this review is to ensure that default values for exposure variables in the IEUBK model are scientifically sound and representative of reasonably current lead exposure in the United States.

Expertise Required:
Peer reviewers should have an advanced degree and/or experience in toxicology, mathematics, environmental health, environmental science, or environmental engineering. EPA is seeking peer reviewers with expertise in (1) water consumption; (2) lead toxicokinetics and toxicokinetics modeling; (3) risk assessment or exposure assessment. Familiarity with the IEUBK model is beneficial. No more than one candidate peer reviewer will be selected from the same agency, consulting firm, or university.

Peer Review Charge Questions:
As a peer reviewer, you are asked to assess the adequacy of this document to provide a clear and concise explanation of the scientific issues regarding the evaluation of and recommendation for updating the IEUBK model. Please comment on the use of the approaches and methodologies to derive default values presented in the following technical document: *Estimation of Lead Exposure from Water Sources for U.S. Children: Water Consumption.*

In evaluating the technical document: *Estimation of Lead Exposure from Water Sources for U.S.* Children*: Water Consumption,* please respond to the charge questions below. If changes are to be made, please provide the technical basis for the proposed changes, citing any improvements, publications or literature that supports your response.

Section 1: General Charge Questions

1.1 QUESTION: Is the organization of the document appropriate and is the document logical, clear and concise? Has EPA clearly synthesized the scientific evidence for the updated IEUBK model input values?

COMMENT: The Panel agreed that the CSFII database outlined in the Update Document was appropriate; however, each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support using this database over the 2003-04 and 2005-06 NHANES WWEIA database. The Panel also agreed that the Update Document needs to provide additional information to support using linear interpolation to estimate water consumption by age.

1.2 QUESTION: Does the evidence presented support implementing the revisions to IEUBK model as default values for the US?

COMMENT: The Panel agreed – yes, and noted that the evidence supports changing the IEUBK model default values.

1.3 QUESTION: What are the strengths and weaknesses of approaches and methods employed given the available data?

COMMENT – Strengths: The Panel agreed that using Kahn and Stralka (2009) was appropriate, and that the 1994-96 & 1998 CSFII data was robust. Furthermore, the Panel agreed with the use of total water consumption from consumers-only was the correct approach.

COMMENT – Weaknesses: The Panel noted that the Update Document does not provide sufficient information on choosing the 1994-96 & 1998 CSFII over the 2003-04 and 2005-06 NHANES WWEIA. One reviewer noted that linear interpolation may not reflect non-linear trends in child development or water consumption over time.

1.4 QUESTION: Given the data available, what additional technical considerations can you recommend in the derivation of default values? Is EPA using appropriate models, datasets and assumptions on which to base a scientifically credible decision?

COMMENT: The Panel agreed that the CSFII database outlined in the Update Document was appropriate; however, the reviewers agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support using this database over the 2003-04 and 2005-06 NHANES WWEIA database. The Panel also agreed that the Update Document needs to provide additional information to support using linear interpolation to estimate water consumption by age.

1.5 QUESTION: Are you aware of any other significant data/studies that are relevant and should be included or referenced in this document? Please identify any additional studies that should be considered in the assessment of the IEUBK model values.

COMMENT: One reviewer recommended reviewing the Exposure Factors Handbook (U.S. EPA, 2011).

Section 2. Specific Charge Questions

This document recommends replacing the current, age-specific IEUBK model default water consumption value (based on U.S. EPA, 1997) with the CSFII 1994-96 & 1998 data as analyzed by Kahn & Stralka (2009).

2.1 **QUESTION:** Kahn and Stralka (2009) derived mean and percentile estimates of age-specific, daily water consumption rates from the 1994-96 and 1998 Continuing Survey of Food Intakes by Individuals (CSFII) [as reported in USDA (2000)].

2.1.1 Do you agree with the use of the CSFII (1994-96, 1998) data to estimate water consumption vs. the most recent NHANES survey?

COMMENT: The Panel agreed that additional information was needed on how these datasets were compared before agreeing that these were appropriately chosen.

2.1.2 Are the methods and procedures set forth in Kahn and Stralka (2009) adequate to ensure that scientifically valid water consumption values are derived?

COMMENT: The Panel agreed that the method discussed in the section on Kahn and Stralka (2009) was adequate.

2.2 **QUESTION:** U.S. EPA (2009) recommends the value derived from Kahn and Stralka (2009) "Estimated direct and indirect community water ingestion; all individuals (i.e., Community water, All individuals)" be used to represent water consumption in the United States.

2.2.1 Do you agree with the document's selection to use of "All water Sources, Consumers Only" to represent water consumption?

COMMENT: The Panel agreed – yes. One reviewer added that these data are more relevant and more conservative.

2.2.2 Please comment on the selection of the overall population and the various subpopulations at risk (e.g., children, "consumers", "all individuals")

COMMENT: The Panel agreed with the selection of the subpopulations at risk was appropriate.

2.2.3 Do you agree with using linear interpolation to pair Kahn and Stralka (2009) age specific data to the IEUBK model age groups vs. time weighted averages?

COMMENT: The Panel agreed that the Update Document should provide additional information on linear interpolations.

3.0 QUESTION: Do you agree that the recommendation that the new age-specific default values are appropriate, nationally representative estimate of water consumption in the United States to use as the basis for a default value in the IEUBK model?

COMMENT: The Panel agreed that the Update Document should provide additional information on linear interpolations.

4.0 QUESTION: Do you have any recommendations for additional analysis of the data? Please provide any additional data, concepts, or other considerations that would provide support for the age-specific values.

COMMENT: The Panel agreed that the CSFII database outlined in the Update Document was appropriate; however, each reviewer agreed that the Update Document needs to be reorganized for clarity and that additional information is needed to support using this database over the 2003-04 and 2005-06 NHANES WWEIA database. The Panel also agreed that the Update Document needs to provide additional information to support using linear interpolation to estimate water consumption by age.

Section 3: Recommendations

Based on your reading and analysis of the information provided, please identify and **submit an explanation of your overall recommendation for the updating the water** consumption variable in the IEUBK model.

1. Acceptable as is
2. Acceptable with minor revision (as indicated)
3. Acceptable with major revision (as outlined)
4. Not acceptable (under any circumstance)

COMMENTS:

- *Reviewer 1: Acceptable with minor revision (as indicated). "As stated above, I believe the case for updating the consumption values as proposed could be strengthened with the addition of certain details not currently included in the document and careful consideration of the details surrounding the linear interpolation of values from Kahn and Stralka."*

- *Reviewer 2: Acceptable with minor revision (as indicated)*

- *Reviewer 3: Acceptable with minor revision (as indicated)*